IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED COMPANY and EDEN BIODESIGN, LLC, Plaintiffs, v. MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS, INC., and SUN PHARMACEUTICAL INDUSTRIES LIMITED, Defendants.	)	C.A. No. 19-1727 (RGA) (Consolidated)

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO STRIKE CERTAIN TRIAL TESTIMONY OF DR. CORY BERKLAND

Defendants challenge Dr. Berkland's testimony related to a passage in the specification about the mixing of excipients with eluxadoline to prepare "solid preformulation compositions" that are then formulated into capsule or tablet dosage forms. JTX-002 (Ex. A), at column 12, lines 52-68. (D.I. 463)[1]. The challenged testimony includes responses to questions from the Court (Tr. 412:13-413:6) and Defendants' cross-examination (Tr. 428:25-429:3; 429:8-431:12).

Defendants' motion should be denied. Dr. Berkland's testimony on this topic responded to opinions of Defendants' own expert, Dr. Richard Gemeinhart, presented for the first time on redirect at trial. Regardless, Defendants' claims that they did not receive Dr. Berkland's opinions on "solid preformulation compositions" prior to trial are incorrect—the topic of this testimony was in Dr. Berkland's expert report.

[1] Defendants challenge Dr. Berkland's testimony at Tr. 378:9-16; 379:24-380:12; 382:4-383:6; 412:13-413:6; 428:25-429:3; 429:8-431:12.

I. Dr. Berkland's Testimony Responded To A New Opinion Provided By Defendants' Expert Dr. Gemeinhart At Trial

On cross-examination, Defendants' expert Richard Gemeinhart was asked about the section of the specification at column 12, lines 52-68, which uses the phrase "solid preformulation composition" to describe the "homogeneous mixture" of excipients before they are portioned out into tablets or capsules. Ex. A at 12:52-68 ("For preparing formulations of the present disclosure, such as tablets, [eluxadoline] is mixed with one or more pharmaceutical excipients to form a solid preformulation composition containing, in preferred embodiments, a homogeneous mixture of the excipient(s) with the active ingredient."). Dr Gemeinhart admitted that section of the specification explicitly contemplated that colloidal silica is optional:

> Q. So that's referring to – that's referring to mixing these excipients together and the need for a homogenous mixture; right?
> A. **I believe so, yes.**
> Q. Okay. And it's saying that you can choose one or more pharmaceutical excipients, meaning that you don't have to include colloidal silica. It's a choice; right?
> **A. It is a choice to try that.**
> …
> Q. So, this language contemplates that the colloidal silica is optional; right?
> A. **I believe so**.

Tr. 260:5-19 (emphasis added). This admission that the plain language of the specification contemplates that colloidal silica is optional contradicts Defendant Sun's invalidity case, which attempts to argue that the specification requires colloidal silica in every formulation. This admission is also consistent with Dr. Gemeinhart's opinions disclosed in his Opening Expert Report that a "preformulation composition" was this "homogeneous mixture" that is then portioned into tablets or capsules. *See* Ex. B, Gemeinhart Opening Report ¶ 274 ("WO '315 further discloses a method for producing the pharmaceutical compositions comprising eluxadoline . . . WO '315 further discloses that these pharmaceutical carriers are mixed with the eluxadoline to form a solid preformulation containing a homogenous mixture of the eluxadoline.").

Yet, on redirect by Defendants' counsel the next day, Dr. Gemeinhart provided an entirely new opinion in direct contradiction of his Opening Report, testifying that the "preformulation composition" was "the stage where you're testing to see if certain excipients will work well in your final formulation." (Tr. 309:18-310:9.) This new opinion by Dr. Gemeinhart, offered on redirect to try to escape the admission on cross-examination, was never disclosed during expert discovery and contradicts Dr. Gemeinhart's opinions previously disclosed in his Opening Report and on cross-examination. It was in this context that Dr. Berkland's responsive testimony on "preformulation" and the "preformulation composition" described in the specification arose.

II. Dr. Berkland's Opinions Were Disclosed Prior to Trial

In contrast, Dr. Berkland's opinions about this portion of the specification were provided to Defendants on July 15, 2022, in his Responsive Expert Report Regarding the Validity of the Asserted Patents (Ex. C, "Responsive Report").[2] Paragraph 200 of Dr. Berkland's Responsive Report states:

> One of ordinary skill in the art would understand that a separate glidant is not necessary if the goal of achieving a homogenous mixture expressed in the patent specification is reached. *See* ELUXJDG-00002044 at 2044 ("If a major component of the formulation such as the diluent were to possess the necessary degrees of fluidity and compressibility, granulation would be unnecessary [to achieve flow and cohesion]."). A lubricant is often used for direct compression tableting, but the specification also notes that a homogenous mixture can be filled into capsules for which no lubricant is required, so one of ordinary skill in the art would understand that a lubricant would be optional. *See, e.g.*, '179 Patent, at 12:59-64 ("When referring to these **preformulation** compositions as 'homogeneous,' it is meant that the active ingredient are dispersed evenly throughout the composition so that the composition may be readily subdivided into equally effective unit dosage forms such as tablets or capsules."), 13:24-45 (two embodiments are prepared by "filling the blend into capsule shells").

[2] Distinct Responsive Reports were provided to MSN and Sun as a result of confidential information belonging to each Defendant. All confidential information has been redacted from the version of Dr. Berkland's Responsive Report attached as Exhibit C. The disclosures relating to Dr. Berkland's opinions were the same in each of the two Responsive Reports.

(emphasis added). Dr. Berkland's opinions quoted part of the passage of the specification at issue here, at column 12, lines 59-64.[3] Dr. Berkland's report specifically discusses the "preformulation compositions" of the patent specifications in a manner consistent with Dr. Berkland's opinions at trial (and Dr. Gemeinhart's expert report and admission on cross-examination). Furthermore, as explained when the Court asked Dr. Berkland about "preformulations" in the context of the patent specification, the term is used in the specification to indicate mixing solids together and blending them prior to tableting. (Tr. 412:4-413:6.) Dr. Berkland's Responsive Expert Report is replete with reference to the mixing and blending of different solids (fillers, disintegrants, powders) prior to tableting. *See, e.g.,* Ex. C ¶ 248 (discussing Fig. 1 and other disclosures of manufacturing information in the specification); ¶ 206 (discussing the functions of excipients in tablet preparation); ¶ 213 (discussing flow properties in tablet preparation); ¶ 243 (discussing homogeneity and flow properties of a powder blend).

Dr. Berkland's testimony related to the opinions that were previously disclosed in his Responsive Expert Report, consistent with Rule 26(a)(2)(B). It is only Dr. Gemeinhart's testimony

[3] Defendants argue that Dr. Berkland "admitted he never previously disclosed" an opinion relating to "preformulation." D.I. 463. This is a mischaracterization of Dr. Berkland's testimony on cross-examination (Tr. 430:3-23):

> Q: Okay. But you did not disclose in your expert report any opinions with regard to the preformulation process discussed in the patent; right?
>
> A**. I did as it pertains to the mixing of ingredients. The word "preformulation" might not have been used, but certainly I opined repeatedly on the mixing process.**
>
> . . .
>
> Q. What I'm getting at is in your expert reports you didn't disclose any opinion that the term "preformulation" in the patents is being used differently than how a skilled artisan would understand that term from references like Remington's. You did not offer an opinion like that; correct?
>
> A. **I did not use that word in my reports that I recall, but my testimony here still stands. It's very clear in that section what it means, and it's not teaching preformulation of testing, the stability of an active, comparing that when you combine it with different ingredients, and a screening process.**

on redirect, contradicting his Opening Report, that was a new opinion. Defendants' own case law requires that this motion be denied. *See Forest Lab'ys, Inc. v. Ivax Pharms., Inc*., 237 F.R.D. 106, 116 (D. Del. 2006) (where expert testimony responded to opinions presented for the first time at trial, and the subject was directly addressed in the expert report, the testimony objected to was not beyond the scope of the expert report); *see also Vectura Ltd. v. Glaxosmithkline, LLC,* No. 16-638-RGA, D.I. 276 at 3 (D. Del. April 1, 2019) (denying motion to strike expert opinion that "reiterate[d] his opinions from his supplemental report") (citing *Dow Chem. Co. v. Nova Chems. Corp. (Canada),* 2010 WL 2044931, at *2 (D. Del. May 20, 2010)).

For these reasons, Defendants' motion should be denied.

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February 3, 2023

CERTIFICATE OF SERVICE

I hereby certify that on February 3, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 3, 2023, upon the following in the manner indicated:

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